Exhibit A

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

In re: PHARMACEUTICAL INDUSTRY AVERAGE
WHOLESALE PRICE LITIGATION

UNITED STATES OF AMERICA ex rel.	)
VEN-A-CARE OF FLORIDA KEYS, INC.	)
Plaintiff	)
v.	) CIVIL ACTION
	) No. 05-11084-PBS
DEY, INC., et al	)
Defendants	)
	)

REBUTTAL REPORT OF PROFESSOR W. DAVID BRADFORD, Ph.D.

May 7, 2009

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A. Qualifications and assignment

A.1. Qualifications

1. I am presently employed at the University of Georgia, where I am the Busbee Chair of Public Policy and Professor in the Department of Public Administration and Policy. I have over 17 years of research experience in the area of health economics in general, much of which has focused on insurance, and the role of incentives and regulations on economic efficiency in particular. I have been principal investigator on 15 funded grants and projects. Several of these projects have focused on the functioning of various components of Medicaid, and involved working directly with Medicaid agency personnel in another state. As of this writing, I have published 45 articles in peer-reviewed publications, have another 30 reports and other publications, and serve as an Editor of the journal *Health Economics Letters*, and am an Associate Editor of the journal *Health Economics*. My curriculum vita was attached as Appendix A to my Expert Report.

A.2. Assignment

2. On March 6, 2009, I submitted an "Expert Report" in this matter. Subsequently on April 23, 2009, plaintiff experts Dr. Mark Duggan and Dr. Stephen Schondelmeyer submitted Rebuttal Reports. In this "Rebuttal Report" I respond to the issues raised by Dr. Duggan and Dr. Schondelmeyer. I am being compensated for my time in this matter at a rate of $525 per hour.

3. I have reviewed depositions, documents, and data produced in this litigation, as well as a variety of publicly available information. The materials I relied upon in my Expert Report were listed in Appendix B of my Expert Report. Additional materials I have considered in this Rebuttal Report are listed in Appendix A. I reserve the right to update my analysis if additional information becomes available. In addition, I reserve the right to supplement or modify my opinions, if warranted, and to prepare additional supporting materials, such as summaries, graphical exhibits, or charts.

B. Overview

4. After reviewing the Rebuttal Reports of Dr. Duggan and Dr. Schondelmeyer, I continue to stand by the opinions offered in my Expert Report dated March 6, 2009. Indeed their Rebuttal Reports do not even address several central opinions, that were (among others) presented in my report:

- It was no secret that generic entry in prescription drug markets lowers prices substantially over time
  - Payers such as Medicare and Medicaid were aware of this and took steps to encourage generic substitution
  - These programs encouraging generic substitution generally saved payers money
- Dey's Wholesale Acquisition Cost ("WAC") has a meaningful relationship with transaction prices
  - WAC also has a practical significance as a list price, and generally tracks transaction prices
  - An economically significant fraction of Dey's sales through wholesalers were at or above WAC
- Dey's Average Wholesale Price ("AWP") is treated as a requirement for market entry, is not generally updated after product launch, and has no relationship to WAC after launch
- State Medicaid prescription drug programs have chosen to rely on private pharmacy networks to provide drugs to the beneficiaries
  - The economics of these programs are driven by the requirement to guarantee access for Medicaid beneficiaries
  - Pharmacy cost studies (both independent and performed for state Medicaid programs) have long documented that a portion of the drug payment is not for the drug at all, but rather covers a portion of the cost of dispensing
- Medicaid was well informed about the differences between AWP, WAC, and pharmacies' acquisition costs for prescription drugs
  - States have substantial flexibility to design their Medicaid programs: variation in payments made by state Medicaid programs is generally a result of local political and economic factors

- States that relied on Dey's WAC for pharmacy payments paid considerably less than those that did not, and any state could have elected to use WAC

- Like Medicaid, Medicare has an access requirement that drives the economics of its program
  - Government studies specific to the drug classes at issue in this matter detail the extent to which Medicare's drug payments exceeded these providers' acquisition costs and many other studies detail the shortfall in payment for services
  - Congress periodically revisited the amount of payment on inhalation drugs (including Dey's drugs) in light of these studies, but ultimately decided to leave payments largely unchanged until 2003 when it enacted the MMA
  - Changes due to the MMA illustrate the extent to which Medicare drug payments built in an implicit service fee payment

5. The issues that Dr. Duggan raises in his Rebuttal Report flow primarily from two fundamental errors. The first is that he repeatedly fails to recognize that policy is a matter of deliberate state and federal choice. Any causal analysis in this case would need to take this into account. The second is a fundamental misconception that patterns of industry behavior from the single-source ("branded") pharmaceutical sector can be applied without modification to the multi-source ("generic") pharmaceutical sector. I will demonstrate that Dr. Duggan's various rebuttal points follow primarily from these two fundamental misconceptions. I also note that in many instances Dr. Duggan mischaracterizes my analyses and opinions and argues against "straw-man" arguments that he himself built up.

6. Dr. Schondelmeyer's Rebuttal Report relies heavily on eight criteria he suggests for evaluating prices as a basis for reimbursement. Published in his 2004 Abt report, these criteria do not, to my knowledge, appear to be part of any Medicare or Medicaid reimbursement rules.[1] In fact, his eight criteria are internally inconsistent, and could never be fully satisfied by any single price. In other words, Dr. Schondelmeyer's rebuttal lays out a final test with the effect that every candidate price must fail. His report appears to illustrate this problem since he argues that several bases like WAC, ASP, and AMP, which are actively used or proposed for use as a basis for reimbursement by Medicaid and Medicare, do not pass his test.

[1] Indeed, as his activities on behalf of pharmacy associations in opposition to CMS' proposed adoption of AMP for reimbursement appear to illustrate, even CMS seems to ignore some of his criteria.

C. Issues raised by Dr. Duggan

7. Dr. Duggan does not address one of the fundamental mistakes in his analysis: he does not consider the fact that Medicaid agencies chose the reimbursement policies based on careful and deliberative processes which were generally well-informed by data. In fact, his statement that, "State governments had the adjudication algorithms that they did…" completely ignores his own admonition to "hold other factors constant".[2]

8. One of the key points I make in my Expert Report is that Dey's WAC has practical significance as a list price, and generally tracks transaction prices. Dey provided this information to everyone through the pricing compendia. It is not merely an academic question whether States could have used this information for reimbursement – many states really did use this information. In general I find that States that chose alternative bases other than WAC paid more for Dey's drugs. In other words, the information that Dey made available cannot alone explain variation in the amounts that states paid for Dey's drugs. As my reviews of the Arkansas and Kentucky examples illustrate, there are many economic and political factors unrelated to the allegations in this case that play a decisive role in the determination of drug payments. In his difference calculating exercise, Dr. Duggan does not control for even a single alternative explanation for the differences in the level of payment.

9. The second fundamental error that Dr. Duggan makes is that he applies standards to generic pharmaceutical prices that are only appropriate for branded pharmaceutical markets, and which are certainly not appropriate for generic pharmaceutical markets. Underlying all of Dr. Duggan's calculations and rebuttal points is the implicit assumption that the expected WAC to AWP mark-up for Dey's drugs should have been 25%. Nowhere does he present any analysis to support this expectation, or why it makes sense. It does not. As I illustrate in my Expert Report, the fact that this relationship does not hold for generics is obvious upon simple examination of the published AWP and WAC values in the pricing compendia (FirstData Bank, Redbook and Medi-Span). In my Expert Report I presented considerable evidence that there is no consistent relationship between WAC and AWP for generic drugs. However, Dr. Duggan has not responded to any of those analyses.

[2] Rebuttal Report of Mark G. Duggan, United States District Court for the District of Massachusetts, Civil Action No. 05-11084-PBS, April 23, 2009, at 2, 10.

10. Finally, many of Dr. Duggan's rebuttal points are not about my opinions at all, but rather about "straw man" arguments that he has constructed. One example of this is the first paragraph under "Medicaid Dispensing Fees" in his rebuttal.[3] Nowhere in my report do I make the argument attributed to me by Duggan in the first sentence, yet after setting up this straw-man, Dr. Duggan then "knocks it down" by arguing against it. This misleading and incorrect reading of my testimony pervades Dr. Duggan's rebuttal. I point out other examples below.

C.1. Holding all else equal

11. The first issue raised by Dr. Duggan in his Rebuttal Report relates to his methodology of calculating damages. Interestingly, he now appears to acknowledge that his calculations are essentially damage estimates.[4] Dr. Duggan defends his methodology of mechanically calculating damages as the difference between actual payments and payments using alternate prices for Dey drugs. Dr. Duggan contends that it is common in applied microeconomics to "focus on the direct rather than the indirect effects".[5] I will address the articles he cites in support of this assertion below. First I point out the standard for damages calculation as explained in "Reference Manual on Scientific Evidence":

> The characterization of the harmful event begins with a clear statement of the harmful event and its effect on the plaintiff, which alone is not sufficient. It must also include:
>
> - a statement about the economic situation absent the wrongdoing;
> - a characterization of the causal link between the wrongdoing and the harm the plaintiff suffered; and
> - a description of the defendant's proper behavior.[6]

12. As the first requirement makes clear, any damages estimate needs to clearly characterize the economic situation in the counterfactual, or 'but-for,' world. In fact, the Reference Manual makes clear that, "In more complicated situations, the damages analysis may need to focus on how an entire industry would be affected."[7] Thus, contrary to Dr. Duggan's assertions it is the proper

[3] Rebuttal Report of Mark G. Duggan, United States District Court for the District of Massachusetts, Civil Action No. 05-11084-PBS, April 23, 2009, at 5.

[4] In his initial report, Dr. Duggan characterized his calculations as DIFFERENCES. However, in his Rebuttal Report Dr Duggan refers to 'damage to the government'. See Rebuttal Report of Mark G. Duggan, United States District Court for the District of Massachusetts, Civil Action No. 05-11084-PBS, April 23, 2009, at 11.

[5] Rebuttal Report of Mark G. Duggan, United States District Court for the District of Massachusetts, Civil Action No. 05-11084-PBS, April 23, 2009, at 2.

[6] Hall, Robert E. and Victoria A. Lazear, "Reference Manual on Estimation of Economic Losses in Damages Awards," Reference Manual on Scientific Evidence, 2000, at 286.

[7] Hall, Robert E. and Victoria A. Lazear, "Reference Manual on Estimation of Economic Losses in Damages Awards,"

standard to adequately characterize the counterfactual world 'but-for' the defendant's conduct. Dr. Duggan's Expert Report does not meet the criteria. Instead, Dr. Duggan suggests that any number of indirect effects is possible. That is true. Consequently, it is the role of the economic expert calculating damages to adequately characterize the 'but-for' world and take into account the most important relevant effects – of which volume changes in the face of price changes is certainly one relevant effect for economic analyses. Dr. Duggan creates the false impression that since not all possible effects can be taken into account, only his so called 'direct effect' is relevant.[8] That is not the standard in damages calculations or in economics.

13. Nonetheless, I assessed Dr. Duggan's 'but-for' world in my Expert Report. My analysis showed that marginal pharmacies would incur losses in the 'but-for' world with Dr. Duggan's alternate prices. Dr. Duggan has not responded to this evidence in his rebuttal. Furthermore, according to Dr. Duggan's flawed standard and methodology, any alternate price can be evaluated only in terms of its "direct impact". As a mechanical exercise of Dr. Duggan's standard and methodology, even the 'direct effect' of alternate prices that are zero can be calculated without any consideration to its feasibility. Clearly the zero alternate price 'but-for' world is infeasible and would fail to meet the basic standard of damages calculation.

14. In defense of his position that one can ignore first-order effects, Dr. Duggan cites an article he published in the *Journal of Public Economics* in 2004. In that article he calculates the effect of managed care enrollment by California Medicaid enrollees on annual spending. Interestingly, Dr. Duggan uses what is known as an "instrumental variables" estimator to conduct his analysis. This way of measuring the effect of managed care enrollment is used precisely because there are other things changing in addition to managed care enrollment, and without taking those changes into account, the model would be biased, and yield misleading results. He explains in this article on page 2551 that: "Identifying the effect of managed care enrollment in this program is difficult for two reasons. First, … those who choose to enroll will differ in unobservable ways from those who do not. Second, … it is plausible that a change in health and thus in the demand for medical care services caused the change."[9] In the face of these two difficulties, Dr. Duggan needed a model that would "net out" these alternative sources of change. He used an instrumental variable exactly

Reference Manual on Scientific Evidence, 2000, at 288.

[8] The Reference Manual makes clear that it is not necessary to analyze miniscule effects. But Dr. Duggan has made no attempt to analyze any other effect besides his so called "direct effect".

[9] Duggan, Mark, "Does contracting out increase the efficiency of government programs?: Evidence from Medicaid HMOs," Journal of Public Economics, Volume 88, 2004, at 2549-2572.

to do this; in other words, the model he chose controls for the other major simultaneous changes that were taking place along with the main effect he wanted to measure - in order not to mismeasure his main effect. Thus, the citation that Dr. Duggan provides in his rebuttal contradicts his own assertion that one can ignore simultaneous effects due to alternate price changes.

C.2. Medicaid utilization

15. Another objection raised by Dr. Duggan relates to the Medicaid utilization of Dey drugs in the "but-for" world with his alternate prices.[10] It is standard to account for changes in quantity (utilization in this case) due to changes in price (reimbursement rates in this case) in damages calculations. Again, the reference manual makes clear the need to take this effect into account.[11] Dr. Duggan has not undertaken such an analysis for Dey drugs at issue. Instead, he points to an example of an Abbott drug which is not relevant for Dey. Abbott and Dey's published prices are significantly different and Dr. Duggan analogy is moot.

C.3. "Dey is too small" argument

16. At various points in his rebuttal report, Dr. Duggan argues that Dey drugs at issue were only 26 out of 25,000 NDCs and consequently too few to necessitate changes in payment policies.[12] Dr. Duggan's argument is flawed at several levels. The first flaw stems again from Dr. Duggan's inadequate consideration of the counter-factual world. As I have already mentioned, in my Expert Report I demonstrated that Dr. Duggan's alternate prices are infeasible as marginal pharmacies would incur substantial losses. In fact, a large fraction of pharmacies would incur losses under Dr. Duggan's alternate prices. Dr. Duggan has not responded to this larger point.

17. Implicit in Dr. Duggan's 'Dey is too small' argument is that Medicare/Medicaid would not revise payments in reaction to one manufacturer's pricing. However, this is exactly what Dr. Duggan's difference calculations assume - where everything is held constant except an alternate price that is applied to just one manufacturer – Dey. Dr. Duggan has not established any basis for selectively

[10] Rebuttal Report of Mark G. Duggan, United States District Court for the District of Massachusetts, Civil Action No. 05-11084-PBS, April 23, 2009, at 4-5.

[11] Hall, Robert E. and Victoria A. Lazear, "Reference Manual on Estimation of Economic Losses in Damages Awards," Reference Manual on Scientific Evidence, 2000 at 288. See, for example, Nieberding, James F., "Lost Profits and Price Erosion in Patent Infringement Cases: Implications of Crystal Semiconductor," Journal of Forensic Economics, Volume 16, 2003, pp. 37-49. See also Epstein, Roy J., "The Market Share Rule with Price Erosion: Patent Infringement Lost Profits Damages After Crystal," AIPLA Quarterly Journal, Volume 31, Number 1, 2003.

[12] Rebuttal Report of Mark G. Duggan, United States District Court for the District of Massachusetts, Civil Action No. 05-11084-PBS, April 23, 2009, at 3, 5.

applying the alternate price standards to Dey only. As I reviewed in detail in my Expert Report, Dey's published prices conformed to the well understood norms of the generic industry.[13]

18. However, if Dr. Duggan's alternate price standard is to be applied to all generic manufacturers then marginal pharmacies would incur losses as I have already discussed.[14] Thus, in Dr. Duggan's alternate price standard world, pharmacies facing losses on each generic prescription sold may respond by supplying only branded prescriptions, and thus substantially driving up the Medicaid and Medicare expenditures on prescription drugs. My initial assessment stands: Dr. Duggan's alternative prices would either lead to unacceptable reductions in access or large increases in total spending. Interestingly, this point is made by the plaintiff expert Dr. Schondelmeyer in his rebuttal, where he states that WAC is an infeasible basis for reimbursement because it fails to "provide adequate compensation to providers and pharmacies" and fails to provide "incentives for pharmacies or providers to supply drugs."[15] As I demonstrate in my Expert Report, Dey's WAC is above the AMP (since Dey's WAC is an undiscounted invoice price). Further, in my Expert Report I have demonstrated that Dr. Duggan's alternative prices are essentially identical to the AMP.[16] Thus, since Dr. Schondelmeyer himself rejects the WAC as too low to be a feasible price, and since Dr. Duggan's alternative prices are equivalent to the even-lower AMP, Dr. Schondelmeyer himself rebuts Dr. Duggan's alternative prices as infeasible.

C.4. Medicaid dispensing fee

19. Another issue raised by Dr. Duggan relates to the Medicaid dispensing fees. Again, Dr. Duggan's discussion began with a misrepresentation of the discussion in my report. In particular, Dr. Duggan states that "…A related point that Dr. Bradford makes on pages 52-59 of his report is that, if Dey had reported more truthful AWPs for complaint products, the state Medicaid agencies would have adjusted their dispensing fees to offset the reduction in pharmacies' ingredient cost

[13] Expert Report of W. David Bradford, United States District Court for the District of Massachusetts, Civil Action No. 05-11084-PBS, March 6, 2009 at Figure 3, Figure 11, and related discussion in section C.

[14] Presumably, Dr. Duggan believes that his alternate price were the appropriate standard to use for all and not just for Dey drugs. In fact he has used similar alternate price standards for Abbott and Roxane drugs in his reports in related litigation. Dr. Duggan's workpapers in Dey-Roxane scenarios reveal that he is applying similar alternate price standards to Roxane drugs.

[15] Rebuttal Report of Stephen W. Schondelmeyer, United States District Court for the District of Massachusetts, Civil Action No. 05-11084-PBS, April 23, 2009, at 17.

[16] Expert Report of W. David Bradford, United States District Court for the District of Massachusetts, Civil Action No. 05-11084-PBS, March 6, 2009 at 131.

profits".[17] There is no such statement in those pages. Instead in those pages I review considerable evidence that there are overall ingredient and dispensing cross-subsidies built into the state Medicaid payments. I reviewed evidence on cross-subsidy based on more than a dozen articles, studies, and depositions. Dr. Duggan has not responded to any of the facts supporting my opinion.

20. At a more fundamental level, Dr. Duggan has not responded to the evidence that States have made informed choices to have the cross-subsidy between ingredient and dispensing cost built into their payment system. Thus any changes to payment ingredient payments would have to be offset by changes to dispensing payments. Plaintiff expert Dr. Schondelmeyer has echoed similar opinions elsewhere "… reform of the drug product cost component of the payment system must be considered in association with reform of other components of the payment system."[18]

21. Instead, Dr. Duggan again repeats his argument that essentially boils down to "Dey was too small" for Medicaid to revisit dispensing fee payments as a consequence of changes to ingredient payments for Dey drugs. I have already discussed the flaws of this argument.

22. Additionally, Dr. Duggan asserts that several states lowered drug payments without altering dispensing payments.[19] Dr. Duggan presents this as evidence against cross-subsidy. On the contrary, these examples corroborate my opinion that states chose to adjust the ingredient cost and leave the dispensing fee alone because it is the overall payments to the providers that matter. As I demonstrated in my report, states rarely revise dispensing fees upward even though the dispensing costs are clearly increasing over time.[20] Instead, states mostly revise only ingredient payments. Thus, the states are implicitly building cross-subsidy into their payment system.

23. Furthermore, in the examples asserted by Dr. Duggan, he fails to consider that the ingredient payment changes made by the states themselves are endogenous decisions. In other words, the states' decisions to revise only one payment component do not provide evidence against cross-subsidy. A more instructive test is to evaluate episodes when ingredient payment changes are exogenous to the states' decision. For example, Deficit Reduction Act ("DRA") of 2005 has

[17] Rebuttal Report of Mark G. Duggan, United States District Court for the District of Massachusetts, Civil Action No. 05-11084-PBS, April 23, 2009, at 5.

[18] Schondelmeyer, Steven W. and Marian V. Wrobel. "Medicaid and Medicare Drug Pricing: Strategy to Determine Market Prices," Abt Associates, Inc., August 30, 2004, at 7.

[19] Rebuttal Report of Mark G. Duggan, United States District Court for the District of Massachusetts, Civil Action No. 05-11084-PBS, April 23, 2009, at 7.

[20] Expert Report of W. David Bradford, United States District Court for the District of Massachusetts, Civil Action No. 05-11084-PBS, March 6, 2009 at Figures 14, 15, 17 and 22.

proposed requiring states to lower ingredient cost payments to the AMP.[21] As a result, several states have proposed increasing dispensing fees substantially if the DRA legislation takes effect. In fact, in 2007 and 2008, several states, including Maine, Massachusetts, and Ohio have enacted legislation that would automatically increase the dispensing fee if and when the lower ingredient payments due to the DRA go into effect.[22] Another instructive episode is when Medicare decided to revamp the payment system from an AWP-based system to an ASP-based system as part of the Medicare Modernization Act ("MMA"). In this episode, Medicare substantially increased dispensing payment levels to compensate for reduced drug payment levels. I have discussed this in detail in my Expert Report.[23]

C.5. Massachusetts algorithm

24. Dr. Duggan states that using the Massachusetts payment formula as a benchmark for other states is "inappropriate".[24] Dr. Duggan's argument that "state governments had the adjudication algorithm that they did"[25] is a tautological statement that fails to consider the choices made by the states. Dr. Duggan does not address the considerable evidence that I reviewed in my Expert Report that shows that states make informed choices.

25. Dr. Duggan does not address the fact that several other states, besides Massachusetts, chose to use WAC for drug payments, as I discussed in my report.[26] These WAC-based states generally achieved lower drug payment rates. Clearly, WAC-based drug payments were an option available to all states. Nonetheless, many states made informed choices to have alternate payment rates based on their needs and political bargaining among stakeholders at the state level. I discussed this process in detail for Kentucky and Arkansas and I also highlighted this process for several other

[21] Senate Bill 1932, Deficit Reduction Act of 2005, Sec. 6001, "Federal Upper Payment Limit for Multiple Source Drugs and Other Drug Payment Provisions." This legislation has not been implemented due to various legal challenges.

[22] For Maine, see "An Act Regarding MaineCare Pharmacy Professional Fees," Chapter 590, Sec. 1. 22 MRSA §3194, 123rd Legislature, available at www.mainelegislature.org/legis/bills/bills_123rd/chapters/PUBLIC590.asp. For Massachusetts, see "Division of Health Care Finance and Policy," Chapter 182 of the Acts of 2008, 4100-0060, available at www.mass.gov/legis/laws/seslaw08/sl080182.htm. For Ohio, see "Increase in Fiscal Year 2009 Dispensing Fee for Multiple Source Drugs," Section 309.31.16, Amended Substitute House Bill Number 119, 127th General Assembly, available at www.legislature.state.oh.us/BillText127/127_HB_119_EN_N.html.

[23] Expert Report of W. David Bradford, United States District Court for the District of Massachusetts, Civil Action No. 05-11084-PBS, March 6, 2009 at 117-119.

[24] Rebuttal Report of Mark G. Duggan, United States District Court for the District of Massachusetts, Civil Action No. 05-11084-PBS, April 23, 2009, at 10.

[25] Rebuttal Report of Mark G. Duggan, United States District Court for the District of Massachusetts, Civil Action No. 05-11084-PBS, April 23, 2009, at 10.

[26] Expert Report of W. David Bradford, United States District Court for the District of Massachusetts, Civil Action No. 05-11084-PBS, March 6, 2009 at 76-103.

states in my report. Dr. Duggan fails to address the considerable evidence of state choices. Instead, his difference methodology attributes these state choices to Dey.

26. Dr. Duggan similarly states that it "is clearly inappropriate" for Medicare to use WAC.[27] Again, Dr. Duggan does not address that Congress and CMS made informed choices to use an AWP-based payment system for Medicare program. Congress could have legislated a WAC-based system like many state Medicaid agencies successfully did.

C.6. Use of wholesaler data

27. Dr. Duggan criticizes my use of the wholesaler data by suggesting that Cardinal data is not representative. In my analyses I used the Cardinal and the McKesson wholesaler data. Cardinal and McKesson are two of the three largest nationwide drug wholesalers, which together account for more than 90% of the wholesale market.[28]

28. Dr. Duggan's criticism of Cardinal wholesaler data is premised on the assumption of an AWP-to-WAC spread of 25%. In my report I presented considerable evidence that this norm does not apply to generic drugs and this fact is well known. Dr. Duggan does not address this evidence. Instead he just proceeds with his arguments that are critically based on this premise. Thus Dr. Duggan's comparison of wholesaler averages to Dey transaction data average scaled by 1.25 is unsupported. This comparison makes no sense for generic drugs.

29. Dr. Duggan also notes that Dey would not have access to the wholesaler data. This is true. The point of using wholesaler data is to get an accurate picture of the prices paid by the providers – in particular the marginal providers. As I discussed in my Expert Report, Medicaid and Medicare have chosen to rely on a network of retail providers. Thus, for this payment system to be viable, payers need to consider the cost of drugs to the marginal provider. In my Expert Report I discussed much evidence that access is one of the important considerations for Medicare/Medicaid. Dr. Duggan does not address any of the evidence I discussed. In my Expert Report, I further show that the wholesaler data provides a much more accurate picture of the actual prices paid by the marginal providers. Thus in order to asses the marginal provider's cost of drug, wholesaler data is a better source.

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[27] Rebuttal Report of Mark G. Duggan, United States District Court for the District of Massachusetts, Civil Action No. 05-11084-PBS, April 23, 2009, at 10-11.

[28] AmeriSource Bergen is the third largest wholesaler. See Britt, Russ, "Growing Share of 'Big Three' Gets Federal Attention: Giant wholesalers dominate market, to hit quarter-trillion mark in sales," Market Watch, May 30, 2007.

C.7. Medicare dispensing fee

30. Dr. Duggan also raises issues with my discussion of cross-subsidy in Medicare payments as exemplified by the Medicare Modernization Act ("MMA"). The MMA significantly lowered drug payments while at the same time significantly increasing dispensing payments as I discussed in detail in section E.4 of my Expert Report. Dr. Duggan claims that a proper evaluation of this change in payment system needs to consider all the factors that changed in the process.[29] My discussion in section E.4 does precisely that when I compare actual overall payment levels based on the old system and the new system. This comparison already takes into account all aspects of the old and the new payment system that Dr. Duggan highlights. As I showed in my Expert Report, the actual overall payments, in fact, go up for some of the drugs at issue such as cromolyn sodium and compounded solution of albuterol and ipratropium bromide. Furthermore, I note that overall payment rates for all inhalation drugs combined did not actually change. These are comparisons of the actual payment data based on the old and the new system. Thus, all the aspects of the new payment system that Dr. Duggan raises are already incorporated in this comparison.

31. Some of the new calculations that Dr. Duggan has presented on this issue in his rebuttal suffer from some other basic shortcomings. For example, Dr. Duggan has not appropriately taken into account the different payment levels for albuterol and ipratropium bromide compounded solution under both the new and the old Medicare payment system. In his calculations, Dr. Duggan always treats albuterol and ipratropium bromide separately. However, the most common inhalation drug combination reimbursed by the DMERCs was for the albuterol and ipratropium bromide as a compounded solution. Dr. Duggan has not evaluated these claims appropriately. Furthermore, as I mentioned in my Expert Report, after the implementation of MMA, Medicare introduced a new HCPCS at a higher reimbursement level for the compounded solution.

C.7.1. Across state extrapolation

32. Dr. Duggan defends his use of the extrapolation of claims data across states by pointing out that it is common to do so in microeconomics. As evidence he points to several papers that perform across-state extrapolation. A closer look at the papers cited by Dr. Duggan shows that these papers do the extrapolation by first carefully controlling for state differences. For example, the Meyer paper has state unemployment rates and state fixed effects in the models that control for

[29] Rebuttal Report of Mark G. Duggan, United States District Court for the District of Massachusetts, Civil Action No. 05-11084-PBS, April 23, 2009, at 13.

differences across states.[30] Thus in extrapolation exercises across states one must control for all relevant observable state variations. Dr. Duggan has not done so.

33. In my report I presented detailed analysis showing substantial variation across state payment rates. I also showed that different states use different payment algorithms not only with respect to AWP and WAC but also in terms of state MAC, DOJ-prices and other payment bases. Dr. Duggan has not addressed any of this analysis. This variation in state payment rates is the reason that one cannot mechanically extrapolate across states without properly controlling for it.

34. The only support Dr. Duggan provides for his across-state extrapolation is that the 14 states he chose to analyze have similar ratios of states using AWP-based and WAC-based payment systems as the remaining states. As I explained in my Expert Report, states use other payment bases besides AWP and WAC. In fact, less than half the payments are based on AWP and WAC.[31] This point is illustrated by comparing the state-MAC-based payments for the 14 states that Dr. Duggan analyzes against the other 16 states for which claims data is available. My analysis shows that among these 14 states only about 6% of the claims were paid on the basis of state MAC while for the other 16 states about 12% of the claims were paid based on the state MAC. Since the state MAC based payments are usually lower than AWP-based payments, Dr. Duggan's methodology produces larger differences when he extrapolates.

35. A more important point is that, given the detailed analysis I presented in my report that showed wide variation in payment basis used by states, a careful examination of the actual claims data is needed. Any extrapolation that does not appropriately account for this is unreliable.

36. In his Rebuttal Report, Dr. Duggan uses the actual claims data for two states – Wisconsin and South Carolina - for which he was previously extrapolating his differences. Based on his calculations Dr. Duggan finds that the extrapolated differences were lower, hence his methodology is conservative. A careful examination of Dr. Duggan's workpapers reveals that his difference for Wisconsin using actual claims data includes a substantial calculation error. In particular, Dr. Duggan calculated the 'but-for' payments as (AWP – 90%) instead of (AWP – 10%) which was the state payment policy. Simply fixing this error would reduce the differences using claims data below the extrapolated differences. In particular, Dr. Duggan reports that using actual claims data

[30] Meyer, Bruce D., "Unemployment Insurance and Unemployment Spells," Econometrica, Volume 58, Number 4, 1990, at 757-782.

[31] Expert Report of W. David Bradford, United States District Court for the District of Massachusetts, Civil Action No. 05-11084-PBS, March 6, 2009 at 76-103.

increases his differences from $2.57 million to $2.92 million. Fixing the aforementioned error actually reduces his difference to $2.37 million.[32] This represents a 23.2% error in his rebuttal calculations.

37. For South Carolina, Dr. Duggan has included additional data in his Rebuttal Report; thus, he generates higher differences compared to his extrapolated differences in his original report. In his original report, Dr. Duggan calculated a difference of $2.34 million for South Carolina from 1992 to 2007 as reported in his table 29A. In his Rebuttal Report, Dr. Duggan reports a difference of $2.35 using claims data. Review of Dr. Duggan's workpapers show that in his Rebuttal Report he is calculating differences including additional data for the first quarter of 2008. I compared his extrapolated and non-extrapolated differences for the common time frame – 1992 to 2007 - and found that the latter actually produces lower differences. Thus Dr. Duggan's results for Wisconsin and South Carolina are based on a calculation error and an improper comparison.

D. Issues raised by Dr. Schondelmeyer

38. In his Rebuttal Report, Dr. Schondelmeyer cites eight criteria for 'estimating acquisition costs in a manner that could serve as a basis for a reimbursement system for all drug products on the market,' which he then uses to evaluate available alternative pricing bases. Several of these criteria are contradictory: passing some of his tests necessarily means failing at least one of his other tests.

39. The most important contradiction built into Dr. Schondelmeyer's criteria can be found in a comparison of his *adequate compensation* and his *accurate and up to date* criteria. His discussion of WAC on page 17 illustrates the problem. There he points out that if the WAC was *accurate*, for "prices actually charged" then it would not have provided *adequate compensation* to providers without modification. In other words, WAC could only pass his *adequate compensation* test if it does not pass his *accurate and up to date* test. Likewise, as I implicitly point out in my Expert Report, pricing that is *accurate* as a measure of average "prices actually charged" cannot also be *current and up to date* since most price concessions are realized ex-post, and cannot be summarized contemporaneous with transactions.

[32] Dr. Duggan additionally makes decisions regarding exclusions of some Wisconsin claims that are different from the decisions he employed for other states. These different decisions result in difference between from the results reported in figure 42 of my Expert Report.

40. It is also unclear what Dr. Schondelmeyer means by *accurate and reliable*. Again, this is illustrated by Dr. Schondelmeyer's discussion of WAC. He states that WAC "is a price that was intended by Medicaid to reflect actual prices", but nowhere does he cite where Medicaid's intention is spelled out.[33] The key questions here are: actual prices to whom, for what, and at what time? Dey's WAC was largely accurate as the prospective price paid by wholesalers for inventory, as the actual contemporaneous price paid by a significant number (at times a majority) of pharmacies, and as a summary of previous average transaction prices. All of this is documented in my Expert Report. In other words, it is accurate as a list price measure and as a transactional price.

41. Even if a manufacturer, in the early 1990s, were somehow able to forecast the unknowable future interpretations of an industry pricing term like "WAC" that Dr. Schondelmeyer would elaborate in April 2009, it still could never satisfy some of his basic criteria. For example, if a manufacturer were to summarize the average net prices it received for its products, the resulting average price would not accurately reflect the price paid by pharmacies or providers since the manufacturer can only observe the prices it is paid by intermediaries before markups are taken. As a result, it would not meet Dr. Schondelmeyer's be accurate. Further, since wholesaler costs must be covered, this undiscounted WAC would be insufficient as a basis of payment to end providers.

42. Even if a manufacturer were further able to accurately predict wholesaler/distributor markups, and reported those average prices, it would still unavoidably fail Dr. Schondelmeyer's criteria. As I document in my report, actual prices paid by providers for Dey's products vary widely, and averages cannot comprehensively reflect actual prices paid. If, as Dr. Schondelmeyer supposes, non-retail classes of trade pay less than retail pharmacies, then any average that includes those non-retail classes of trade would neither be *accurate* as a measure of the prices that pharmacies pay, nor would it provide *adequate compensation* if used as a basis for payments to pharmacies. This is fundamentally his argument against the use of the AMP as it is defined in the final rule established by CMS its implementation of the 2005 DRA. However, extending this logic by excluding non-retail classes of trade from average prices would lead to *inaccurate*, and perhaps *inflated,* estimates of the prices paid by non-retail providers.

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[33] Rebuttal Report of Stephen W. Schondelmeyer, United States District Court for the District of Massachusetts, Civil Action No. 05-11084-PBS, April 23, 2009, at 17. In fact, the only official understanding of the WAC of which I am aware is the 2003 definition provided in the context of the MMA, which interprets the WAC as a list price (Medicare Prescription Drug Improvement and Modernization Act of 2003, sec. 303(c)(2), §1847(a), 117 Stat. 2066 (2003)). In his Rebuttal Report at page 4, Dr. Schondelmeyer refers to FDB descriptions of AWP and WAC as "list and benchmark prices," which casts some doubt on his interpretation that these are prices "actually charged" (see Schondelmeyer Rebuttal Report, at 17).

43. Dey's products are purchased by many different types of providers in a variety of circumstances at very different prices. Dr. Schondelmeyer provides completely circular and contradictory guidance as to what a manufacturer in these circumstances should have done so as to comply with his eight criteria. Thus, Dr. Schondelmeyer's criteria are themselves infeasible, since they do not permit any price measure (real-world or imaginary) to pass.

May 7, 2009

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Date

Appendix A: Materials considered

Litigation documents

- Rebuttal report of Mark G. Duggan, United States District Court for the District of Massachusetts, Civil Action No. 05-11084-PBS, April 23, 2009 and materials considered.
- Rebuttal report of Stephen W. Schondelmeyer, United States District Court for the District of Massachusetts, Civil Action No. 05-11084-PBS, April 23, 2009 and materials considered.
- Expert report of Lauren J. Stiroh, United States District Court for the District of Massachusetts, Civil Action No. 05-11084-PBS, March 6, 2009.
- Expert report of Robert B. Helms, United States District Court for the District of Massachusetts, Civil Action No. 05-11084-PBS, March 6, 2009.

Academic literature

- Duggan, Mark, "Does Contracting Out Increase the Efficiency of Government Programs? Evidence from Medicaid HMOs," Journal of Public Economics, Volume 88, 2004, at 2549-2572.
- Epstein, Roy J., "The Market Share Rule with Price Erosion: Patent Infringement Lost Profits Damages After Crystal," AIPLA Quarterly Journal, Volume 31, Number 1, 2003.
- Hall, Robert E. and Victoria A. Lazear, "Reference Guide on Estimation of Economic Losses in Damages Awards," Reference Manual on Scientific Evidence, 2000, at 277-332.
- Meyer, Bruce D., "Unemployment Insurance and Unemployment Spells," Econometrica, Volume 58, Number 4, 1990, at 757-782.
- Nieberding, James F., "Lost Profits and Price Erosion in Patent Infringement Cases: Implications of Crystal Semiconductor," Journal of Forensic Economics, Volume 16, 2003, at 37-49.
- Schondelmeyer, Steven W. and Marian V. Wrobel. "Medicaid and Medicare Drug Pricing: Strategy to Determine Market Prices," Abt Associates, Inc., August 30, 2004.

Federal statutes

- "Federal Upper Payment Limit for Multiple Source Drugs and Other Drug Payment Provisions," Senate Bill 1932, Deficit Reduction Act of 2005, Sec. 6001.

Publicly Available Documents

- Britt, Russ, "Growing Share of 'Big Three' Gets Federal Attention: Giant wholesalers dominate market, to hit quarter-trillion mark in sales," Market Watch, May 30, 2007.